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IN THE

Supreme Court of the United States

DR. CHARLES THOMAS SELL, DDS,
Petitioner,

v.

UNITED STATES OF AMERICA,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF FOR THE AMERICAN PSYCHIATRIC ASSOCIATION AND AMERICAN ACADEMY OF PSYCHIATRY AND THE LAW AS *AMICI CURIAE* SUPPORTING RESPONDENT

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The American Psychiatric Association (APA) and the American Academy of Psychiatry and the Law (AAPL) respectfully move for leave to file a brief as *amici curiae* in this case. Although respondent, the United States, has granted consent (by letter filed with the Clerk), petitioner has not.

The APA, with approximately 42,000 members, is the Nation's leading organization of physicians specializing in psychiatry. The APA has participated as *amicus* in many cases involving mental-health issues, including *Kansas v.*

Crane, 532 U.S. 782 (2001), *Olmstead v. L.C. by Zimring*, 527 U.S. 581 (1999), *Kansas v. Hendricks*, 521 U.S. 346 (1997), *Foucha v. Louisiana*, 504 U.S. 71 (1992), *Riggins v. Nevada*, 504 U.S. 127 (1992), *Washington v. Harper*, 494 U.S. 210 (1990), and *Addington v. Texas*, 441 U.S. 418 (1979). It also participated at the court's invitation in *United States v. Gomes*, 289 F.3d 71 (2d Cir. 2002), involving issues similar to those presented here. AAPL, with roughly 2500 psychiatrists dedicated to excellence in practice, teaching, and research in forensic psychiatry, has participated in, *e.g.*, *Crane*, *supra*, *Penry v. Johnson*, 532 U.S. 782 (2001), and *Jaffee v. Redmond*, 518 U.S. 1 (1996).

The members of the APA and AAPL are physicians engaged in treatment, research, and forensic activities, and many of their members regularly perform roles in the criminal justice system. The organizations and their members have substantial knowledge and experience relevant to the issues in this case. Both organizations seek to ensure that the Court has well-grounded facts about antipsychotic medications, including the new generation of medications post-dating *Riggins*, and appreciates the adverse consequences–for the patient, for other patients at an institution, for the legal system's interests–of not giving medications that are the medically appropriate treatment for psychotic illnesses and the only realistic hope of restoring competence.

For these reasons, the APA and AAPL ask that their motion be granted.

Respectfully submitted.

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BRIEF FOR THE AMERICAN PSYCHIATRIC ASSOCIATION AND THE AMERICAN ACADEMY OF PSYCHIATRY AND THE LAW AS *AMICI CURIAE* SUPPORTING RESPONDENT

INTEREST OF *AMICI CURIAE*

Amici's interest is stated in the accompanying motion.[1]

INTRODUCTION

A government can justify involuntary medication to restore a criminal defendant's competence to stand trial on several necessary conditions, most importantly that such medication is medically appropriate for the individual, *i.e.*, warranted on the normal medical grounds balancing the benefits of the medication to the patient against the risks of side effects. The decisions in *United States v. Weston*, 255 F.3d 873 (D.C. Cir. 2001), in *United States v. Gomes*, 289 F.3d 71 (2d Cir. 2002), and in this case allow involuntary medication to restore competence for trial on sufficiently serious charges if the medication is medically appropriate for the individual, it holds a reasonable prospect of serving its purpose of restoring competence, and no realistic alternatives holds a similar prospect of achieving that end. This brief supports that standard.[2] How the medical aspects of that standard apply in a particular case is necessarily a case-specific factual question.

The sufficiency of the government's interest in trying certain charges ultimately requires a value judgment. *Amici* have no distinctive perspective on whether that judgment

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[1] No party authored this brief in whole or in part, and no person except *amici* and their members made a monetary contribution to the preparation or submission of this brief. S. Ct. R. 39.6.

[2] This case presents no question as to capital punishment, which might involve special considerations. Nor does the issue before this Court involve the *procedures* required for involuntary medication; such procedures should recognize that delaying treatment (through years of appeals) can cause not only deterioration in the patient's condition but physical changes in the brain that make later treatment more difficult and less effective.

might vary according to the seriousness of the charges and, if so, what principle might sensibly and workably define any constitutional line. However drawn, the judgment should reflect an accurate appreciation of the medical context and the possible results of refusing medications (*e.g.*, deterioration of condition, increased difficulty of later treatment, warehousing of defendants, loss of evidence and ability to try defendants).

STATEMENT

1. Petitioner, a dentist, has a history of mental illness. Pet. App. 3. He required hospitalization for a psychotic episode in 1982, and he was released following a course of "conventional" antipsychotic medication (haloperidol (Haldol)). JA242; *see* JA151 (second episode: vision of leopard).

In 1997, petitioner was charged with numerous counts of fraud against Medicaid and against private insurance companies, as well as money laundering. He was initially found competent to stand trial and released on bond. At a bond-revocation appearance, he ranted and spat at the magistrate, and the subsequent bond-revocation hearing included evidence of his deteriorating mental condition. New charges of conspiring and attempting to kill a witness and an FBI agent were soon added to the fraud charges. Pet. App. 3, 14. As trial preparations proceeded, petitioner "filed a notice of intent to introduce evidence of a mental disease or defect" (Pet. xii), and his counsel requested a new competency determination. Petitioner was found incompetent based on a diagnosis–by both petitioner's and the government's psychologists–of delusional disorder, persecutory type. Pet. App. 3[3]; *see* Pet. App. 36, JA145,149-51 (describing delusions).

[3] The court of appeals' opinion (Pet. App. 3 n.3) notes that, under the standard classification system set forth in the APA's *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* ["*DSM-IV*"] at 296-301 (1994), a delusional disorder is characterized by the presence, for a month or more, of one or more delusions of a non-bizarre nature, *i.e.*, a fixed, firm, evidence-resistant, false belief in "generally plausible ideas that can conceivably occur in real life" (such as being followed, infected, deceived by one's spouse, etc.); lack of visual or auditory hallucinations (false perceptions) indicative of schizophrenia; and lack of general impaired functioning and of otherwise obviously bizarre behavior. If the delusion is of being persecuted, the diagnosis is of "persecutory" type of delusional disorder. Other types involve delusions about, for example, the condition of one's body or erotic attachments. *Id.* The current *DSM-IV-TR* at 323-39 (2000) ("TR" for "Text Revision") is comparable.

While committed, petitioner was under the care of Dr. DeMier, a psychologist, with Dr. Wolfson the consulting psychiatrist. Both determined, and later testified at an administrative hearing, that antipsychotic medications were likely to restore petitioner to competency and to be "the only way he could be restored to competency." Pet. App. 3. After petitioner refused medications, a medical hearing officer (a psychiatrist) "concluded that antipsychotic medication was the treatment of choice" for his psychotic symptoms. Pet. App. 4; *see* JA143-54.

2. At the judicial hearing, Drs. DeMier and Wolfson, on direct and cross-examination, testified to the following:

- Petitioner has a psychosis. Dr. DeMier had adopted the diagnosis of delusional disorder, persecutory type, when petitioner was found incompetent to stand trial. Dr. Wolfson endorsed that diagnosis tentatively, without yet ruling out schizophrenia as an alternative diagnosis, indicating that the appropriate treatment is the same regardless. JA166-68,228-31,257-60. (Earlier, Drs. DeMier and Wolfson both suggested a possible diagnosis of schizophrenia. JA150.)
- The psychosis, whatever the definitive diagnosis, is best treated with antipsychotic medication, which is "clearly indicated" as "the only treatment that we could reasonably expect to improve [petitioner's] condition," given the lackof effective alternatives, the benefits provided, and the recognized but controllable risks of the medications. JA179; *see* JA168,180 (no effective alternatives), 187-91 (side effects), 191 (improvement unlikely without medication), 220-21 (psychotherapy typically not successful with delusional disorder),

229-30, 235 (therapy may help *after* medication, but unlikely "success or meaningful benefit from other therapy interventions" without medication), 266 (same).

• Without antipsychotic medication, petitioner's condition will likely deteriorate, and delayed treatment will likely take longer to work and not work as well. JA168,231.

• Delusions often respond to antipsychotic medication (JA218,230,280-81), and petitioner "can be restored to competency, as a result of treatment with anti-psychotic medications" (JA179). *See* JA245 ("good chance"), 300-02 (citing period of a few weeks to months). Dr. DeMier had two delusional disorder patients who were treated with antipsychotic medications, one with haloperidol (Haldol), one of the older generation, the other with olanzapine (Zyprexa), one of the newer medications, and saw improvements in both and restoration of competence in one (the one given Haldol). JA178-79,187-88. Dr. Wolfson had an 80% success rate on a somewhat larger group of patients. JA244.

• For delusional disorder, the literature discusses one of the older medications, pimozide (Orap), as beneficial, but the newer generation of "atypical" antipsychotics might now be preferable: they have "substantial advantages," notably their "more benign side effect profile" than the conventional antipsychotics. JA239-41.[4]

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[4] Dr. Wolfson mentioned, among the new "atypical" medications, quetiapine (Seroquel) and olanzapine (Zyprexa), as well as ziprasidone (Geodon or Zeldox), and observed that, once medication is ordered, it is reasonable to give patients a choice among appropriate alternatives. (Flexibility in changing medication, without renewed hearings and delays, also makes medical sense.) Dr. Wolfson noted, in 1999, that the atypicals were available only for oral administration, not for injection, so the atypicals called for patient cooperation. JA241,300-01.

In June 2002, an injectable form of ziprasidone (Geodon) was approved for marketing in the United States. *Physician's Desk Reference* 2601 (57th ed. 2003). In Germany, an injectable form of risperidone (Risperdal), another atypical medication, was approved last summer.

• Haldol allowed petitioner's 1982 release from the hospital; reducing the dose controlled a muscle spasm side-effect. JA242-43.

• Although "there is a conventional wisdom that patients with delusional disorder respond less to medication," Dr. Wolfson's experience and the case reports in the literature actually show favorable results in many cases. JA246.

• There are "some potential unpleasant side effects from antipsychotic medications," just as "there are for most medications that are used in any medical specialty." JA236. Stiffness and restlessness problems can occur with conventional (typical, traditional) antipsychotics, but they can be treated; and possible sedating effects can likewise be dealt with. JA236-37. "[M]ost patents don't have to expect problematic side effects as the cost of having their illness treated and having control of their own thoughts and minds." JA237. As for the potentially serious neuroleptic malignant syndrome, the risk is very small, perhaps 1 in 10,000, and the costs of the continuing illness are much greater. JA238-39.

Petitioner submitted a declaration by Dr. Cloninger, a psychiatrist, recommending against medication. Noting that delusional disorder "is a rare condition," unlike schizophrenia, so that psychiatric experience is limited (JA30), he distinguished medication's effectiveness for schizophrenia and its effectiveness for delusional disorder. After citing a 1988 textbook, he reported finding only one article containing "systematic data * * * about the treatment of a large series of cases of Delusional Disorder," a 1993 article reporting "'a long-term follow up study'" of 72 Norwegian patients, comparing the *long-term* results of a group first admitted to hospitals in 1946-1948 (before antipsychotics were introduced) to a group first admitted in 1958-61 (after the earliest antipsychotics were introduced), and finding no "more favorable outcome" for the latter group. JA30-31. "In other words, there is no evidence that neuroleptics are beneficial for patients with Delusional Disorder." JA31; *see* JA31-32.

Dr. Cloninger, noting petitioner's 1982 treatment with antipsychotic medication, stated that petitioner's "delusions did *not* respond as evidenced by his immediately discontinuing treatment" and that petitioner "regarded that treatment as a terrible experience." JA32.[5] Neuroleptics "always are associated with risk of side effects," and "treatments that carry any risk at all" should not be given involuntarily, he wrote, "in the absence of documented evidence of benefit to the person." JA32. He therefore recommended "treatment * * * limited to basic support and voluntary symptomatic treatment," including "a safe supportive milieu with access to exercise and reading material" and voluntary antidepressant medication (paroxetine (Paxil)). JA32; *see* JA149,294. Dr. Cloninger did not testify and so was not cross-examined.

Dr. Wolfson responded to Dr. Cloninger's brief declaration, criticizing its broad conclusions. The absence of large scale, double blind, placebo control studies–which are impractical with delusional disorder (particularly paranoid) patients–does not support a conclusion that medications are ineffective; and case reports and a statistical analysis of prior studies in fact show significant beneficial response. JA247-49,278-79. Moreover, the 1993 article cited by Dr. Cloninger does not show ineffectiveness. It reports only certain *long-term* results (not short-term effectiveness), based on two groups of patients from the era when only the very first antipsychotic medications were available; the article reserves judgment on how informative even as to long-term

[5] Dr. Cloninger did not address the apparent effectiveness of medication in allowing petitioner's release from the hospital in 1982 and did not explain why *ineffectiveness* was shown by petitioner's discontinuance of medication. Patients stop medications for other common reasons: *e.g.*, the medications did their job and are no longer needed; a patient *believes* the medications are no longer needed or (as with delusional disorder) does not consider himself ill or dislikes side effects. The article cited by Dr. Cloninger recognizes the frequency of "noncompliance" (not taking prescribed medication) with delusional disorder patients. *See* note 6, *infra*.

results the lack of difference between the groups is, noting that delusional disorder patients often do not take their medications over time; and the article notes reports of pimozide's benefits for delusional disorder. JA248-50,278-79.[6]

3. The magistrate (like the medical hearing officer previously) found that, with side effects subject to control, the medical benefits of antipsychotic medication far outweigh any risk, such medication was likely to restore competence (enable petitioner to communicate rationally with counsel), and there were no realistic alternatives. Pet. App. 24-26. The district court, noting the ability to control risks of side effects, found that the record supports the same findings and, hence, the order of medication, also noting the prematurity of concerns about any adverse effects from medications on trial rights. *Id.* at 29-46. The Eighth Circuit drew the same conclusions (*id.* at 7-10), basing the judgment *only* on the fraud and money-laundering charges. Pet. App. 7.[7]

[6] The limited significance of the 1993 article for the question of relevance here–short-term effectiveness of any of the whole range of antipsychotic medications now available, including the 1990s generation–is evident in the article itself. Opjordsmoen & Retterstol, *Outcome in Delusional Disorder in Different Periods of Time*, 26 Psychopathology 90 (1993); JA135-43. The paper notes that "pimozide has * * * been reported to be beneficial" for delusional disorder patients. *Id.* at 90. The paper observes that such patients are "often difficult to treat because of denial, projection and reluctance to take drugs" (*id.*) and that, while delusional disorder might be more resistant to treatment than schizophrenia, "[a]nother explanation might be that there are more problems with compliance [patients' actually taking their medication] in delusional disorder than in schizophrenia," for "[p]aranoid patients are usually very sensitive to all side effects of drugs." *Id.* at 93. The paper notes "the difficulties encountered in doing research in this field," so treatment for this disorder "still seems to be terra incognita, and controlled drug trials are strongly needed." *Id.*; *see also* A. Munro, *Delusional Disorder: Paranoia and Related Illnesses* 229 (1999) ("noncompliance with psychiatric treatment is a common feature of delusional disorder").

[7] In disregarding the other charges (attempt and conspiracy to commit murder), the court merely said: "It is possible that [petitioner's] threats

SUMMARY OF ARGUMENT

The similar analyses of the Eighth, Second, and D.C. Circuits should be followed by this Court. Criminal defendants, like others, have an undoubted liberty interest in avoiding forced bodily intrusions, including any kind of medication, psychiatric or otherwise. But the interest is not absolute, and just as avoiding danger to self or others suffices to justify medically appropriate medication, so should the government interest in restoring competence to stand trial (on charges this Court deems sufficiently serious). There are weighty interests in resolving criminal charges and in avoiding the harmful effects of leaving individuals without needed treatment. The crucial conditions are that the medication be medically appropriate, under the normal medical balancing of benefits and risks (taking account of the manageability of risks); hold a reasonable prospect of restoring competence; and be reasonably necessary to achieve the goal, considering alternatives.

The analysis should be the same whether the needed medication is a psychiatric or nonpsychiatric one. Whether particular medications meet the crucial conditions in a particular case is a matter for case-specific determination based on medical judgments. Those judgments take account of the particular illness at issue and whatever likelihood there is of side effects from the typically short-term use of medications needed for the goal of competence restoration.

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after his first indictment were a manifestation of his delusional disorder * * *." Pet. App. 7 n.8. That rationale for ignoring the murder-related charges is unrelated to the interests justifying medication (adjudicating charges). Moreover, that rationale might bar involuntary medication in any insanity-defense case, no matter how serious the offense. If a defendant charged with *actual* murder claimed insanity based on a mental illness that also makes him incompetent, it could equally be said that "[i]t is possible that [the murder was] a manifestation of his [insanity]." Petitioner himself has raised a mental-illness defense, so even the fraud and moneylaundering might be "a manifestation of" his mental illness.

In particular, they take account of the significant advances in antipsychotic medications post-dating this Court's decisions in *Riggins v. Nevada*, 504 U.S. 127 (1992), and *Washington v. Harper*, 494 U.S. 210 (1990), including the new generation of antipsychotic medications that, as a class, have better side-effect profiles than the earlier medications.

Neither First Amendment interests nor Sixth Amendment trial-right interests should alter the basic judgment about justifying involuntary administration of medically appropriate medication. Such medication typically enhances rather than impairs speech interests, and, in any event, the government justification sufficient for due process analysis would suffice under the First Amendment as well. Likewise, appropriate medication typically enhances rather than impairs a defendant's ability to participate effectively at trial, and, in any event, any concerns about possible sedating or other adverse effects on demeanor or testifying ability are properly considered at a later stage, after competence is restored. The defendant may plead guilty and avoid trial; adverse effects often will not occur at all; and any adverse effects are broadly subject to being controlled by adjustment of medication, so the mere possibility of such effects should not stand in the way of restoring competence.

ARGUMENT

I. THE LEGAL FRAMEWORK OF *RIGGINS V. NEVADA* AND *WASHINGTON V. HARPER*

Based on the longstanding legal recognition of personal autonomy, there is a due process liberty interest in refusing unwanted antipsychotic medication, like any other medication, but the interest "is not absolute." *Weston*, 255 F.3d at 876; *see Riggins*, 504 U.S. at 135; *Harper*, 494 U.S. at 220, 222-23. *Harper* and *Riggins* illustrate the two sides of that principle. *Harper* establishes the sufficiency, for justifying involuntary medication, of the state interest in avoiding danger in a custodial setting, where the medication is medially appropriate. *Riggins* recognizes the constitutional interest

itself by holding, as argued by the APA, that the State must justify involuntary medication, which the State had not been required to do in *Riggins* at all. *Riggins*, 504 U.S. at 136.

Riggins makes clear, too, that this principle is properly enforced in the criminal proceeding itself, rather than in a collateral suit challenging unjustified involuntary medication. It was on that question–a point of disagreement with the dissent (*Riggins*, 504 U.S. at 146 (Thomas, J., dissenting))–that it was relevant for the *Riggins* Court (and the APA) to observe that certain medications, especially if given in high doses, *may* affect a criminal defendant's appearance, and role, as a criminal defendant. *See* APA *Riggins* Br. 12-15; *Riggins*, 504 U.S. at 137; *id.* at 142-43 (Kennedy, J., concurring in the judgment) (quoting APA brief).[8] Indeed, Riggins had been given very high doses of thioridazine (Mellaril), a conventional antipsychotic medication with significant sedating effects that many other medications, both older and newer ones, do not have. *Id.* at 137.[9] Such

[8] Possible side effects, differing even among the conventional medications, include restlessness, "parkinsonism" (characterized by tremors or diminished range of facial expression or slowed movements or speech), and sedation. "There is, however, little reliable evidence that properly used antipsychotic medication has any significant adverse effect on attention or perception. And it is well established that the foregoing side-effects are readily subject to reversal or control by adjusting doses or prescribing counteracting medication." APA *Riggins* Br. 10-11 (citations omitted).

[9] *See, e.g.*, J. Preston, J. O'Neal, & M. Talaga, *Handbook of Clinical Psychopharmacology for Therapists* 178-79 (2d ed. 2001) (tables listing medications, dosages, and side effects); P. Weiden, P. Scheifler, R. Diamond, & R. Ross, *Breakthroughs in Antipsychotic Medications* 94 (1999) (publication of National Alliance for the Mentally Ill) (table of conventional medications and side effects); *id.* at 111 (noting differences in sedating effects even among various older medications, let alone among newer ones; even when sedating effects occur, sometimes those effects end after a few weeks; "[s]edation is very sensitive to dose adjustments"). The dosage of Mellaril given to Riggins was 800 mg, the very highest indicated dose. *Riggins*, 504 U.S. at 129, 131.

potential side effects, being relevant to the criminal trial, justify a demand for state justification in the criminal case.

This point must not be overstated. The Court did not decide, and the APA did not urge, that such potential effects *defeat* a State interest in restoring competence or that they even weigh heavily, given that side effects are broadly subject to being monitored and controlled, whether by switching medications, lowering doses, or taking other action. All *Riggins* decided was that (a) a criminal defendant may insist, in the criminal case, on the State justifying involuntary (medically appropriate) medication and (b) dangerousness in custody is sufficient justification (*Riggins*, 504 U.S. at 135; *Harper*, 494 U.S. at 225-26), while the need to restore competence "might" be (*Riggins*, 504 U.S. at 136). And the entire consideration of antipsychotic medications in *Riggins*, as in *Harper*, was in a medical context now dramatically altered: a new generation of medications has, since 1990, transformed practices in the treatment of psychotic illnesses.

II. THE INTEREST IN RESTORING COMPETENCE TO STAND TRIAL CAN JUSTIFY INVOLUNTARY ANTIPSYCHOTIC MEDICATION IF IT IS MEDICALLY APPROPRIATE

Antipsychotic medication should be treated like other medication. Because an individual has a constitutional interest in avoiding any involuntary bodily intrusion, a justification is required to administer any type of medication to an objecting individual, including one who is incompetent to stand trial. The medical, and legal, judgment should be similar whether, for example, antithyroid medications (with their side-effect risks) are being considered for a thyroid condition like Grave's disease (*see* A. Fauci *et al.*, *Harrison's Principles of Internal Medicine* 2026-27 (14th ed. 1998)) or an antipsychotic medication (with its particular side-effect risks) is being considered for a mental illness. In each case, the individual's side of the constitutional balance is protected by the essential requirement of medical appropriateness of the

particular medication for the individual, considering the treatment benefits and risks. On the other side of the balance, the public interest at issue here (adjudicating serious criminal charges) is a great one; and that interest typically is accompanied by additional interests as well.[10]

In undertaking the analysis, it is critical to bear in mind that virtually all medications, whether psychiatric or non-psychiatric, involve risks of side effects.[11] This commonplace

[10] *Amici* here assume that petitioner's refusal of medication was a competent one. Incompetence to stand trial, involving inabilities to understand proceedings or assist in one's defense (*Godinez v. Moran*, 509 U.S. 389 (1993)), is conceptually and practically distinct from competence to make a rational choice about medication. *See* T. Grisso *et al.*, *MacArthur Competence Assessment Tool for Treatment* (1998); Otto *et al.*, *Psychometric Properties of the MacArthur Competence Assessment Tool-Criminal Adjudication*, 10 Psychological Asssessment 435 (1998); Berg *et al.*, *Constructing Competence: Formulating Standards for Legal Competence to Make Medical Decisions*, 48 Rutgers L. Rev. 345 (1996); Bonnie, *The Competence of Criminal Defendants: Beyond Dusky and Drope*, 47 Miami L. Rev. 539 (1993); N. Poythress, *et al.*, *Adjudicative Competence: The MacArthur Studies* (2002). For an individual who is incompetent to *refuse treatment* (as well as to stand trial), autonomy interests are weakened and state *parens patriae* interests are strengthened. The question here assumes no such special weakening of autonomy interests and addresses the State's interest in restoring competence to stand trial, not other state interests, as justification for involuntary medication.

[11] *See, e.g.*, A. Komaroff, ed., *Harvard Medical School Family Health Guide* 1151 (1999) ("Every medication, including nonprescription drugs, has the potential to cause side effects or adverse reactions."); D. Tapley, *et al.*, eds. *Columbia University College of Physicians & Surgeons Complete Home Medical Guide* 836 (3d rev. ed. 1995) ("All drugs–even aspirin–can have unpleasant side effects in some people."); R. Berkow, *et al.*, eds., *Merck Manual of Medical Information, Home Edition* 26 (1997) ("Most drugs * * * have some undesired effects."; "Since all drugs can harm as well as help, safety is relative. The wider the margin of safety (therapeutic window)–the spread between the usual effective dose and a dose that produces severe or life-threatening side effects–the more useful the drug."; "Some drugs must be used despite their having a very narrow

fact is recognized, for example, in the longstanding law governing drug approval, under which "safety" itself is always a balancing of benefits and risk. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000) ("virtually every drug or device poses dangers under certain conditions"); *id.* at 140 ("safety" under FDCA means that a drug's or device's "probable therapeutic benefits must outweigh its risk of harm").[12] Medical decisions always involve balancing such risks against the benefits of the medication in (a) relieving suffering and (b) improving functioning. *See Weston*, 255 F.3d at 876-77 (medical appropriateness, as judged by professionals, is measured "by examining the capacity of antipsychotic drugs to alleviate [the individual's] schizophrenia (the medical benefits) against their capacity to produce harm (the medical costs, or side effects)"). That balance is part of the medical appropriateness determination itself, as the testimony and findings here confirm, whether the subject is antipsychotic medication for a mental illness or nonpsychiatric medication for a non-mental illness.

A. Antipsychotic Medications Are An Accepted, Often Essential Treatment for Many Psychoses

Antipsychotic medications are not only an accepted but often essential, irreplaceable treatment for psychotic illnesses,

margin of safety."; examples are anticlotting drug, warfarin, and antipsychotic drug, clozapine).

[12] *Id.* at 142 ("drugs are safe within the meaning of the Act because, for certain patients, the therapeutic benefits outweigh the risk of harm"); *United States v. Rutherford*, 442 U.S. 544, 556 (1979) (safety means that the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit"); *FTC v. Simeon Management Corp.*, 532 F.2d 708, 714 (9th Cir. 1976) (per Kennedy, J.) ("many risky medical procedures may be regarded by the FDA as 'safe,' in light of their greater potential benefits."); U.S. Brief in *Rutherford* at 31-32 ("A drug is 'safe,' within the meaning of the Act, if the benefits expected to be achieved through its administration outweigh the costs or risks incurred. No drug is completely 'safe' in the lay person's sense of the word, since every drug—aspirin not excepted—involves risks.") (footnotes omitted).

as most firmly established for schizophrenia, because the benefits of antipsychotic medications for patients with psychoses, compared to any other available means of treatment, are so palpably great compared with their generally manageable side effects. *See Weston*, 255 F.3d at 877 n.2. That was so for the antipsychotic medications prevalent in 1990: *e.g.*, haloperidol (Haldol), thiothixene (Navane), chlorpromazine (Thorazine), thioridazine (Mellaril), or pimozide (Orap). *See* B. Sadock & V. Sadock, *Kaplan & Sadock's Comprehensive Textbook of Psychiatry* ch. 31.17 at 2356-77 (7th ed. 2000) ["*Textbook*"] ("Dopamine Receptor Antagonists (Typical Antipsychotics)"). It remains true with the post-*Riggins* generation of antipsychotic medications, which, while each carrying its own combination of side-effect risks (like virtually every drug), have lower risks of the older drugs' more troublesome side effects. The newer drugs include risperidone (Risperdal), olanzapine (Zyprexa), quetiapine (Seroquel), and ziprasidone (Geodon (elsewhere, Zeldox)). *See Breakthroughs in Antipsychotic Medications* at 94-95; *Textbook* ch. 31.26 at 2455-74 ("Serotonin-Dopamine Antagonists").[13]

1. Conventional Antipsychotic Medications. Even at the time of *Riggins*, before the atypicals, antipsychotic drugs were central to treating both acute and chronic psychoses such as schizophrenia. In 1987, the National Institute of Mental Health concluded that such drugs "remain the primary modality in the treatment of an acute episode or an acute exacerbation of a schizophrenic illness," having "a dramatic effect on the symptoms of schizophrenia (e.g., delusions, hallucinations, and thought disorder) within 4-6 weeks, although improvement may continue well after that interval." Kane, *Treatment of Schizophrenia*, 13 Schizophrenia Bull.

[13] As the *Textbook* chapter titles show, the older medications worked principally through their effect on dopamine, one of the neurotransmitter amino acids, while both dopamine and serotonin (another neurotransmitter amino acid) are affected by the newer generation.

133, 134, 142 (1987). The drugs were similarly central to long-term treatment of chronic psychosis, being "of enormous value in reducing the risk of relapse and rehospitalization." *Id.* at 143. Medication was commonly essential: "The available data do not support the feasibility of substituting any psychotherapeutic strategy for drug treatment on an indefinite basis." *Id.* at 142; *see* Kane *et al.*, *Clozapine for the Treatment-Resistant Schizophrenic*, 45 Archives Gen. Psychiatry 789 (1988) (earliest of newer medications).

That accepted standard of care, even in 1990, fully accounted for side effects, reflecting the devastating character of the illnesses being treated.[14] This Court reviewed some of the side effects of the older antipsychotic medications in

[14] *See* Paul, "The New Pharmacotherapy of Schizophrenia," in A. Breier *et al.*, *Current Issues in the Psychopharmacology of Schizophrenia* xvii-xviii (2001) (schizophrenia afflicts ½-1% of the world's population, "is associated with a high degree of morbidity and mortality" (including a 10% suicide rate), and "the illness almost invariably requires institutionalization and both acute and chronic intervention (at great emotional and financial expense), " but "effective pharmacotherapy is available for most patients with this disorder"); J. Gorman, *The Essential Guide to Psychiatric Drugs* 197-98 (3d ed. 1997) ("there is no debate that schizophrenia is a horrible illness. It strikes people in late adolescence to early adulthood and often never goes away. * * * [Most] endure many hospitalizations, are unable to work, and have little social interaction. Schizophrenia devastates the early adult years of most patients. The situation is almost equally grim for families * * *. Living with a [person with schizophrenia] is usually a full-time and harrowing job. The patient lives in his or her own world, entertaining bizarre ideas and listening to voices. He may talk without making sense, pace the floors all night, and occasionally become violent or threatening. Parents, acting as if they have toddlers, are afraid to leave their [children with schizophrenia] alone. They, like the patient, become prisoners of the illness. So, although schizophrenia may seem romantic or interesting to philosophers, it is plainly awful to its victims. * * * The hallmarks of schizophrenia are hallucinations, delusions, thought disorder, and disorganized behavior. These[] are often called positive symptoms. There are also negative symptoms such as abnormal affect, loss of motivation, and social isolation.").

Harper, 494 U.S. at 229-30 (describing acute dystonia; akathisia; neuroleptic malignant syndrome; and tardive dyskinesia); *see Riggins*, 504 U.S. at 134. But it was true even in 1990 that "[m]ost of th[e] side-effects *** may be controlled by lowering dosages or by adding another medication; such side effects ordinarily cease when antipsychotics are discontinued." APA *Riggins* Br. 10 (footnote on tardive dyskinesia omitted); *see Weston*, 255 F.3d at 877 ("While there are potential side effects, the professional judgment of the medical experts was that 'each of these potential side effects is generally manageable.'"); note 9, *supra* (even among conventional medications, wide variation in sedating effects). With respect to tardive dyskinesia, two facts are especially significant for short-term treatment of most psychoses: *first*, "[a]lthough the risk of TD is frightening and serious, so is the risk of allowing acute psychosis to remain uncorrected" (*Essential Guide to Psychiatric Drugs* at 219); *second*, "TD virtually never develops after only a few weeks or months of taking the antipsychotic drugs." *Id.*[15]

2. The Newer Antipsychotic Medications. The medical context "has changed substantially during the 1990s." *Textbook* at 1199. With the newer medications, it is all the more firmly true that medications are commonly essential to

[15] Tardive dyskinesia appears to develop at rate of "about four percent per year of cumulative drug exposure for at least the first five years" with the older medications. Kaye & Reed, *Tardive Dyskinesia: Tremors in Law and Medicine*, 27 J. Am. Acad. Psychiatry & L. 315, 315 (1999); *see* Kane & Malhotra, *Clinical Psychopharmacology of Schizophrenia and Psychotic Disorders*, in G. Gabbard, ed., *Treatments of Psychiatric Disorders* 1027, 1038 (3d ed. 2001) ("Prospective studies have suggested an incidence of 5% per year of antipsychotic exposure in young adults, with a substantially higher incidence in elderly persons. The majority of cases are mild and not necessarily progressive even with continued antipsychotic exposure. However, some patients develop a severe and disabling form of the condition. If medication can be discontinued, the prognosis is often favorable, but discontinuation is often not feasible.").

responsible treatment of psychoses like schizophrenia.[16] The newer "atypical" antipsychotic drugs not only have proved effective for many people (including some for whom typicals did not work well) but are widely recognized to "have a 'more favorable side effect profile'" as a class than the older medications, as the testimony in *Weston* established and Dr. Wolfson's testimony in this case reiterates. *See Weston*, 255 F.3d at 877 n.3 (noting side effects *as a class*; importantly, *amici* note, side effects differ even among the atypicals).

It is important to avoid generalizations that either oversimplify or get ahead of the ever-continuing research on particular medications.[17] Nevertheless, it is clear that major

[16] *See also* Kane & Malhotra, *supra*, at 1027-28 ("Pharmacological treatment is a critical component in the short- and long-term management of schizophrenia."); *Handbook of Clinical Psychopharmacology for Therapists* at 177 ("Antipsychotic medications have truly revolutionized the treatment of psychotic disorders. Their effectiveness is so vastly superior to previous treatments that they have ushered in a new era in the treatment of severe mental illnesses."); Baldessarini, *Psychophar-macology*, in A. Nicholi, Jr., ed., *The Harvard Guide to Psychiatry* 444, 450 (3d ed. 1999) (effectiveness within a few days or weeks; "acute psychosis or exacerbations of chronic psychosis, especially of schizophrenia, are routinely treated with antipsychotic medications in adequate doses"); Marder, *Antipsychotic Medications*, in A. Schatzberg & C. Nemeroff, *The American Psychiatric Press Textbook of Psychopharmacology* 309 (2d ed. 1998) ("these drugs have become standard treatments in psychiatry and medicine"); Geddes, *Prevention of Relapse in Schizophrenia*, 346 N.E.J. Med. 56 (2002) ("the preponderance of the evidence now supports the use of risperidone as a first-line treatment for patients with schizophrenia, both to induce remission and to prevent relapse"). (The last-cited article updates Geddes, *Atypical Antipsychotics in the Treatment of Schizophrenia: Systematic Overview and Meta-Regression Analysis*, 321 British Med. J. 1371, 1375 (2000) (atypicals and typicals comparably effective and tolerable overall; atypicals cause fewer "extrapyramidal" side effects; recommending use of typicals first).)

[17] Sources describing particular drugs and what is known about them, including their own risks of side effects, include the *Textbook* sections cited above; *The Essential Guide to Psychiatric Drugs*, *supra*; *Breakthroughs in Antipsychotic Medications*, *supra*; A. Breier *et al.*, eds.,

progress has been made, particularly in reducing the traditionally most troublesome side effects (and also in helping previously hard-to-treat psychoses), by the introduction of the newer atypical medications in the last decade. *See Weston*, 255 F.3d at 886 n.7 ("Antipsychotic drugs have progressed since Justice Kennedy discussed their side effects in *Riggins*. There is a new generation of medications having better side effect profiles."). Each such medication, like any medication, has its own side-effect risks: for example, for some of them, a risk of weight gain and, from long-term use, a risk of diabetes. But the side-effect profiles are significantly improved from the older generation, and the improvements include what strongly appears, from an accumulating body of evidence, to be a substantial reduction of the risk of tardive dyskinesia.[18] As one paper noted, because of the lower risks

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Current Issues in the Psychopharmacology of Schizophrenia (2001); and the APA's *Practice Guideline for the Treatment of Patients With Schizophrenia*, 154 Am. J. Psychiatry No. 4 (April 1997 Supp.); *see also* Rivas-Vazquez *et al.*, *Atypical Antipsychotic Medications: Pharmacological Profiles and Psychological Implications*, 31 Prof. Psychology: Res. & Prac. 628 (2000) ("newer antipsychotic agents may make patients with schizophrenia more amenable to psychosocial and rehabilitative interventions").

[18] Kane & Malhotra, *supra*, at 1027 ("Overall, the new-generation antipsychotic drugs do provide clear advantages in terms of reducing adverse effects (particularly drug-induced parkinsonism, akathisia, and, it is hoped, tardive dyskinesia)."); *id.* at 1034-35 (for olanzapine, a 1997 study showed "a significantly lower incidence of treatment-emergent dyskinesia among olanzapine-treated patients") (citation omitted); *id.* at 1035 ("In summary, as a class, the second-generation antipsychotics clearly have advantages over conventional drugs particularly in the area of adverse effects (with the exception of weight gain [a side effect of some, but not all, of the newer drugs])."); Kaye & Reed, *supra*, at 316 ("after over 10 years of clinical use, there are still no confirmed cases of TD from exposure to clozapine"; for risperidone, olanzapine, and quetiapine, "evidence for increased safety" is "impressive. The apparent incidence of TD with risperidone is between 0.03 and 2.4 percent. With olanzapine the

of neuromuscular problems, the standard of care for schizophrenia is rapidly moving toward the newer antipsychotics, even with their own side effects, as the first line of treatment.[19]

3. Delusional Disorder. The effects of medication for a particular individual with a particular diagnosis is a matter for a case-specific factual determination, as was made based on expert testimony at multiple judicial levels in this case. *Cf. Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949) (under "two court" rule, Court rarely disturbs concurrent findings, or case-specific applications of accepted legal principles, of two courts below); *Neil v. Biggers*, 409 U.S. 188, 193 n.3 (1972). Nevertheless, some general information about delusional disorder–the relatively rare disorder (compared to schizophrenia) that is, at least tentatively, involved in this case–is useful in considering the record here. As that record indicates, the evidence respecting treatment of delusional disorder is less definitive than for schizophrenia

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incidence of TD is 0.5 to 1 percent compared with 4.5 to 7.5 percent for haloperidol.") (footnotes omitted)

Aside from the reduced risk of tardive dyskinesia from the new medications, there is some evidence, since *Riggins*, that the abnormal involuntary movements characteristic of tardive dyskinesia are at least partly the result of the psychotic illness itself, *rather than* of the medications. Gervin *et al.*, *Spontaneous Abnormal Involuntary Movements in First-Episode Schizophrenia and Schizophreniform Disorder: Baseline Rate in a Group of Patients From an Irish Catchment Area*, 155 Am. J. Psychiatry 1202 (1998); Khot *et al.*, *Not All That Moves Is Tardive Dyskinesia*, 148 Am. J. Psychiatry 661 (1991); *see* Weiden, *supra*, at 109 (tardive dyskinesia can worsen upon stopping older medications, which may, during use, suppress symptoms of the disease).

[19] Kaye & Reed, *supra*, at 331; *see* Pinals & Buckley, *Novel Antipsychotic Agents and Their Implications for Forensic Psychiatry*, 27 J. Am. Acad. Psychiatry & L. 7 (1999). Progress in this field is continuing. *See* note 4, *supra* (new injectable atypicals); Brook *et al.*, *Intramuscular Ziprasidone Compared With Intramuscular Haloperidol in the Treatment of Acute Psychosis*, 61 J. Clinical Psychiatry 933 (2000); Geddes (2002), *supra*.

and other more common psychotic illnesses (which also are less resistant to collecting systematic data); fairly recent summaries can be found in the pertinent chapter of the 2000 *Textbook* at 1243-64 (Manschreck, *Delusional Disorder and Shared Psychotic Disorder*), and the 1999 Munro book, *supra*. Against this background, the testimony of Drs. DeMier and Wolfson, including the responses to Dr. Cloninger, supports the findings about medication here–its medical appropriateness, the prospects for restoring competence, and the lack of realistic alternatives.

Patients with delusional disorders are relatively uncommon, have often not been identified in a distinct diagnosis, are outside many clinicians' experience, and have been difficult to study systematically because they "do not regard themselves as mentally ill and actively oppose psychiatric referral." *Textbook* at 1243, 1244, 1248-50. Although, for such reasons, delusional disorder "has generally been regarded as resistant to treatment" (*id.* at 1262), "[l]imited but growing evidence supports * * * [delusional disorder's] distinctiveness from schizophrenia and mood disorder as well as its treatability." *Id.* at 1243; *id.* ("recent reports suggest that favorable responses to psycho-pharmacologic and psychotherapeutic interventions are more common than previously thought"). Although the disorder can remit over time, it also can be lifelong; it generally develops by "gradual, progressive involvement with the delusional concern"; meanwhile, patients "suffer" and "often feel demoralized, miserable, isolated, and abandoned." *Id.* at 1261-62. Non-pharmacologic treatments have "not been studied enough to justify recommendation." *Id.* at 1262. Medication has been more successful, though "the results required to support this practice *empirically* have been only partially obtained." *Id.* at 1262 (emphasis added). In particular, case reports and studies based on them–which are "especially valuable" as evidence (*id.* at 1263) given the difficulties of obtaining more systematic studies–have shown success with pimozide

(Orap), an older medication, lesser success with other typical neuroleptics, and some success with "atypical" medications. *Id.* at 1251, 1253, 1262-63.

Dr. Munro, a leading researcher in the field, likewise noted in 1999 the "gloomy outlook" among "physicians not familiar with the modern literature"; observed that this "illness which, if allowed to go untreated, is certainly both severe and disabling"; and concluded that "[m]any anecdotal treatment results, and a small number of double-blind drug trials, appear to show a consensus that delusional disorder, despite its traditional resistance to treatment, can now be regarded as an eminently treatable illness." *Munro* at 3-4, 6. He added that "pimozide tends to be the most widely used drug" and "appears to give very good results, but * * * the evidence is still insufficient to know whether it is inherently superior to other neuroleptics in treating delusional disorder." *Id.* at 6.

Munro explained that delusions "can fluctuate in intensity over time, even in the absence of treatment"; and treatment does not "necessarily *cure* delusions, but * * * can allay them to the point where they are either no longer evident or interfere minimally with normal functioning." *Id.* at 32. One reason the reports of treatment are still mostly "anecdotal" (*i.e.*, reports of small numbers of cases, not statistically large samples), *id.* at 227, is "the notorious reluctance of delusional disorder patients to engage in psychotropic drug trials." *Id.* at 229; *id.* at 237 ("delusional disorder patient's excessive wariness and suspicion" may make "conventional double-blind drug trials * * * all but impossible"). The reports "overall add[] up to a refutation of the belief that delusional disorder is irremediable," and "[v]irtually all of these reports refer to psychopharma-cological treatment." *Id.* at 227; *see id.* at 234 (no evidence "suggests that psychological approaches are effective in treating actual delusional disorder"). As to doses and duration: starting with a very low dose (1-2 mg daily) of pimozide or other medication, and gradually increasing (up to 4-6 mg), "it takes about two

weeks of continuous, adequate treatment to produce significant amelioration of the delusion," though "in some patients it may be six weeks or longer." *Id.* at 233. As of 1999, pimozide was "the best documented and most cost effective intervention in delusional disorder." *Id.* at 238. Although "[t]reatment aspects of delusional disorder are in crying need of good, experimentally-based drug trials" (*id.* at 240), Munro concluded in 1999: "delusional disorder, properly diagnosed and adequately treated, has an optimistic outlook. Whatever the neuroleptic employed, the overall rate of response, total or partial, is approximately 80 per cent, an outcome that compares well with any other in psychiatry. It is clearly desirable to identify and, if possible, treat cases." *Id.* at 237.[20]

B. The Interests Supporting Medication Are Weighty

This Court has often described the "compelling interest in finding, convicting, and punishing those who violate the law." *Moran v. Burbine*, 475 U.S. 412, 426 (1986); *accord Texas v. Cobb*, 532 U.S. 162, 172 (2001); *Gray v. Maryland*, 523 U.S. 185, 202 (1998) (Scalia, J., dissenting); *McNeil v. Wisconsin*, 501 U.S. 171, 181 (1991); *Richardson v. Marsh*, 481 U.S. 200, 210 (1987); *Garrett v. United States*, 471 U.S. 773, 796 (1985) (O'Connor, J., concurring); *Winston v. Lee*, 470 U.S. 753, 762 (1985). More pointedly, the interest in adjudicating the charges, one way or the other, is a great one. *See Riggins*, 504 U.S. at 135-36 (quoting *Illinois v. Allen*, 397 U.S. 337, 347 (1970) (Brennan, J., concurring): "[c]onstitutional power to bring an accused to trial is fundamental to a

[20] *See* Felthous *et al.*, *Are Persecutory Delusions Amenable to Treatment?*, 29 J. Am. Acad. Psychiatry & L. 461 (2001) (describing reasons for lack of systematic studies; summarizing evidence of positive results of medication; noting limitations–seven patients, short treatment, long-term delusions–of Silva, *Effects of Pimozide on the Psychopathology of Delusional Disorder*, 22 Prog. Neuro-Psychopharmacol. & Biol. Psychiatry 331 (1998)). The chapter relied on by Dr. Cloninger (JA91-135), from 1988, notes that "[a]ntipsychotic medication may be useful." JA106.

scheme of 'ordered liberty' and prerequisite to social justice and peace"). The Court has also recognized the public interest in *prompt* adjudication. *See Flanagan v. United States*, 465 U.S. 259, 264-65 (1984); *Barker v. Wingo*, 407 U.S. 514, 519-20 (1972).

Importantly, these interests supporting restoration of competence rarely stand alone when medication is medically appropriate. Although a defendant may judge the risk of conviction an overriding one, or otherwise wish to forego the benefits of needed medication, the Court should not ignore the real costs of leaving a defendant untreated when he needs such treatment. These include the costs to the defendant himself (a concern that is especially strong if competency to make treatment decisions is also impaired). Languishing without treatment leaves in place the suffering and impairment of functioning that psychoses cause–the core reasons for medication qualifying as medically appropriate. In addition, there is evidence (though it is not definitive) that delaying treatment, like allowing other kinds of disease to fester, can cause physical alterations (here, in brain structures) to make a psychotic condition worse, harder to treat, and more likely to recur after treatment.[21] The costs for the individual include, as well, the other individual harms from needless institutionalization the Court recognized (at the APA's urging) in *Olmstead v. L.C. by Zimring*, 527 U.S. 581 (1999).

Though treatment should not be given unless appropriate for the individual, of course, other individuals also are ad-

[21] *See* J. Preston, *supra*, at 112 ("there is now evidence to support the notion that being psychotic is damaging to the brain"); Loebel *et al.*, *Duration of Psychosis and Outcome in First-Episode Schizophrenia*, 149 Am. J. Psychiatry 1183 (1992); Wyatt, *Neuroleptics and the Natural Course of Schizophrenia*, 17 Schizophrenia Bull. 325 (1991); Baldessarini, *supra*, at 451 ("There is some evidence that abrupt discontinuation of antipsychotic medication is associated with more frequent and earlier relapses * * *."); *Textbook* at 38-40, 1198 (untreated episodes may create brain structures worsening illness and making it more refractory).

versely affected by leaving the individual untreated. The families of severely disturbed individuals suffer many consequences of their loved ones' psychoses, through both the loss of self and the behavior such psychoses cause. And when an individual is in an institution, leaving him untreated can be unhealthy for other individuals served by the institution, even when the individual is not physically dangerous. The treatment environment is important, as reflected in the emphasis over the past decades on de-institutionalization and improvement of institutions. That environment is harmed, *e.g.*, impairing calm and confidence, by exposure to the agitation, disruption, senseless communication, and languishing associated with untreated psychoses. *See* Amarasingham, *Social and Cultural Perspectives on Medication Refusal*, 137 Am. J. Psychiatry 353 (1980); Abroms, *Defining Milieu Therapy*, 21 Archives Gen. Psychiatry 553 (1969).

Leaving untreated a defendant who is incompetent to stand trial harms other public interests too. If enough time passes, the government may lose its ability to try the charges at all. With competence unlikely to return without medication, there is a genuine potential for defendants to refuse medication for lengthy periods–the more serious the charges, perhaps, the greater the potential–while waiting for evidence to grow stale or the cases against them otherwise to weaken. And since refusal of medication often will leave the individual confined, the government will incur mounting costs of institutionalization. A collateral consequence of institutionalizing many patients who cannot be given medically appropriate treatment, moreover, is damage to the government's ability to hire and retain professional staff, forced to act more as jailers or custodians than as caregivers.

Under 18 U.S.C. §§ 4241, 4246, there is a realistic possibility of long-term, open-ended confinement of many criminal defendants found incompetent to stand trial. Confinement is allowed if incompetence remains and "release would create a substantial risk of bodily injury to another person or serious

damage to property of another." *Id.* § 4246. The relevant risk is *not* judged by reference to restraints possible in prison. Many criminal defendants who are incompetent to stand trial would remain confined indefinitely under this statute (let alone under broader standards Congress might choose to adopt for defendants incompetent only as a result of their own refusal of appropriate medication). Without needed medication, restoration of competence is unlikely according to the best medical prediction at the time of decision, and in any event the possibility is not bounded by any knowable duration. Given the dearth of comparably effective alternatives to antipsychotic medication, a defendant may remain incompetent to stand trial indefinitely.

Whatever constitutional questions might arise on a full analysis, indefinite confinement in likely circumstances of incompetence based on refusal of medication is not precluded by *Jackson v. Indiana*, 406 U.S. 715 (1972). Jackson was not being held under a finding of dangerousness, so the decision is inapplicable to standards for confinement based on danger. In any event, all *Jackson* held was that, when an individual was confined (outside normal civil commitment processes) for the purpose of restoring competence, that confinement became impermissible if the individual *could not* be restored to competence, because such confinement is not reasonably related to its purpose. But *Jackson* does not restrict the confinement of an individual who voluntarily prevents his own restoration to competence–for whom confinement *is* reasonably related to the purpose of the confinement.

C. First Amendment and Fair Trial Interests Should Not Alter the Constitutional Balance

1. Speech Interests. First Amendment interests do not alter the constitutional balance for antipsychotic medications that are justified under the due process standard already discussed. The medications, when appropriate, aim to clear the hallucinations and delusions produced by psychosis, or to allow the patient to recognize and control their dominating

influence. They thus alleviate the mental suffering and functional impairments, producing "*loss* of freedom," characterize severe mental illness. *See DSM-IV-TR* at xxxi (emphasis added). The medications, when properly used to treat the severely mentally ill, positively *promote* First Amendment interests by enhancing abilities to concentrate, read, learn, and communicate. The evidence contradicts the "view of these drugs as mind-altering, thought-inhibiting, or destructive of personality in a negative sense. In fact, the beneficial effects of the medication on complex aspects of mentation suggest that the opposite conclusion is true: the medications reinforce the most important aspects of mental functioning."[22] Relatedly, as the APA explained in *Riggins*, "[t]he mental health produced by antipsychotic medication is no different from, no more inauthentic or alien to the patient than, the physical health produced by other medications, such as penicillin for pneumonia (which might be labeled 'synthetic fitness' or 'synthetic health')." APA *Riggins* Br. 9; *see Riggins*, 504 U.S. at 141 (Kennedy, J., concurring in the judgment).[23]

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[22] Gutheil & Appelbaum, *"Mind Control," "Synthetic Sanity," "Artificial Competence," and Genuine Confusion: Legally Relevant Effects of Antipsychotic Medication*, 12 Hofstra L. Rev. 77, 119 (1983); *see* Felthous, *supra*, at 466 ("Rather than mind restricting, the medication is mind liberating."); Appelbaum & Gutheil, *Rotting With Their Rights On*, 7 Bull. Am. Acad. Psychiatry & L. 306, 310 (1979).

[23] "These days, when people are treated with modern psychiatric medication, one of the most common remarks therapists hear once the medications begin to take effect is, 'I am beginning to feel like myself again.' This is a very important point to emphasize. Although some medications do have unpleasant side effects, and some misuse of these drugs certainly continues, the goal of appropriate psychiatric treatment is twofold: (1) to reduce human suffering and (2) to promote the development and expression of autonomy. This a far cry from the chemical straitjackets of the mental hospitals' back wards in the 1950s." J. Preston, *Consumer's Guide to Psychiatric Drugs* 14 (2000)

In any event, the analysis does not change by adding any First Amendment interest to the personal-autonomy interest protected by due process standards. "[G]overnment regulation is sufficiently justified if it is within the constitutional power of the Government; if it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest." *United States v. O'Brien*, 391 U.S. 367, 377 (1968). Those conditions are met if the due process justification is established–if the medication is needed to serve the public interest in adjudicating serious criminal charges, an interest unrelated to suppressing any free expression.

2. Fair Trial Interests. The Court (and the APA) in *Riggins* acknowledged that antipsychotic medication *can* create adverse effects on a defendant's role at trial, thus triggering a duty of justification on the part of the government enforceable in the criminal case. But the interest in avoiding such effects does not alter the basic weight of the competence-restoration justification. In the majority of cases, resolved by guilty plea, effects at trial are immaterial. Moreover, unless there is an unusual reason to know otherwise at the outset, legitimate interests in avoiding unjustified adverse inferences by the jury can readily be addressed *after* competence is restored. Finally, an interest in "appearing psychotic" does not deserve significant weight.

The effect of administering appropriate medication will, in all likelihood, be the very opposite of *impairing* trial rights. Such medication likely will "'enhance some of Weston's trial rights, particularly his right to consult with counsel and to assist in his defense.'" *Weston*, 255 F.3d at 883 & n.6. Moreover, such medication "will more likely improve," not impair, "Weston's ability to relate his belief system to the jury." *Id.* at 884. And, while a criminal defendant has a "right to be present at trial in a state that does not prejudice

the factfinder against him"–which could occur through, *e.g.*, a "flattened emotional affect" from some medication–"medication will likely enhance rather than impair [a defendant's] right to a fair trial," including by restoring the ability to present more appropriate facial responses. *Id.* at 885.

Critically, although "[t]he possibility of side effects from antipsychotic medication is undeniable," the ability of "treating physicians and the district court to respond to them substantially reduces the risk they pose to trial fairness." *Weston*, 255 F.3d at 885. The effects can be monitored and typically controlled (*id.* at 885-86), whether through choosing among the medications (which have widely varying risks of side effects on movement, sedation, etc.), reducing dosages, adding a counteracting medication, or otherwise. Physicians' ability to control such effects, moreover, can be directly supplemented—for purposes of alleviating any illegitimate adverse effect on the defense–by the district court's management of the case. The district court can inform the jury of the medication and its effects and can allow testimony on those effects, disabusing the jury of adverse illegitimate inferences from demeanor. *Id.* at 886. With those bases for addressing fair-trial concerns, the *Weston* court sensibly concluded: "Whether antipsychotic medication will impair Weston's right to a fair trial is best determined when the actual effects of the medication are known, that is, after he is medicated." 255 F.3d at 886 n.8. The *Gomes* court and the Eighth Circuit here reached the same sound conclusion.

A case involving a defense of insanity should not be materially different. The constitutional analysis should focus on reliable evidence, not tactical considerations that, though they may be real, exploit *unfair* or *unreliable* evidentiary inferences. With the ability to monitor and control harmful demeanor effects, the ability to inform the jury of medication's effects, and the availability of other more probative evidence on the issue of insanity, there is a relatively "small risk" that a jury would take a medicated defendant's "testi-

mony (if he decides to testify) as an indication that he must have been sane at the time of the crime, or that he is making it up, or that he deserves no sympathy." *Weston*, 255 F.3d at 884. The same assessment applies to the defendant's general appearance at trial, whether as witness or at counsel table.

Any interest a defendant may have in affirmatively appearing before the jury in an unmedicated state does not warrant being given significant weight here. Most basically, where medication is needed to restore competence, denying medication cannot generally produce the trial (with defendant unmedicated) that this interest invokes. Seemingly, the defendant would have to take medication to become competent, then waive his competence at trial (if waiver is lawful), then stop medication and return to incompetence for trial. But petitioner objects even to the first step; in any event, there is surely a strong interest in not *requiring* the judicial system to try an incompetent defendant.[24]

In addition, the evidentiary significance of demeanor in legitimately establishing the defendant's insanity at the time of a crime is not particularly strong. An individual's psychotic state may not be evident in his or her appearance or demeanor. A person who appears calm may be no more or less insane–"as a result of a severe mental disease or defect, [he] was unable to appreciate the nature and quality or the wrongfulness of his acts" (18 U.S.C. § 17)–than an individual who exhibits anxious or active forms of behavior. Moreover, even without medication, a defendant's courtroom demeanor may differ from what it was at the time of the charged offense: time, the courtroom setting, or the structured prison environment can alter demeanor. The evidentiary nexus between demeanor and sanity is relatively weak.

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[24] Such a trial might be unlawful. *See* 18 U.S.C. § 4241(a); *Godinez*, 509 U.S. at 396; *Drope v. Missouri*, 420 U.S. 162 (1975); *Pate v. Robinson*, 383 U.S. 375 (1966); *see* Pet. App. 7 ("The government may not constitutionally bring an incompetent defendant to trial * * *.").

At the same time, other evidence diminishes any adverse effect from the absence of an unmedicated demeanor and more reliably addresses the issue of insanity at the time of the offense. The jury may be educated, by the judge or by expert witnesses, about the fact that the defendant is taking medication and why he may not "appear psychotic." The defendant may be videotaped in an unmedicated state close in time to the offense. Psychiatric experts and other witnesses will often provide more reliable evidence about the defendant's state of mind at the time of the offense. *See also Weston*, 255 F.3d at 884-85 (a defendant has no general right "to replicate on the witness stand his mental state at the time of the crime," giving examples of intoxication and heat of passion). The constitutional analysis of administration of needed medication, in sum, should not be altered for insanity-defense cases.

CONCLUSION

Antipsychotic medications should be treated no differently from other medications. When medically appropriate (based on a benefit-risk balance), and reasonably likely and reasonably needed to restore competence, such medication may constitutionally be compelled for that purpose in a case involving a serious enough offense.

Respectfully submitted,

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